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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/685,329	07/23/96	RAGUSE	B 1847/21

18M1/1119

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EXAMINER

CHIN, C

ART UNIT	PAPER NUMBER
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1802

DATE MAILED: 11/19/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/11/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-21 is/are pending in the application.
Of the above, claim(s) 22-2 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-21 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-22 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I - claims 1-21 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that since claims 51-61 are in the same class and subclass as claims 1-21, claims 51-61 should be examined along with claims 1-21. This is not found persuasive because the method of claims 51-61 forms a different product than the method of claims 1-21 and thus would require a different search strategy.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 U.S.C. § 112

3. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the lipids (lipid A, lipid C, and lipid D) defined on page 2 of the specification, does not reasonably provide enablement for the use of any lipids in the solutions recited in claims 1 and 13 for coating an electrode. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As recited in claims 1 and 13, the claimed methods use any lipid as linker lipid A and membrane spanning lipids C and D. However, page 2 of the specification requires linker lipid A to have certain specific regions (a benzyl disulfide attachment region, a hydrophilic region, etc) and membrane spanning lipids C and D to have specific attachment, hydrophilic, and hydrophobic regions to enable formation of a membrane on an electrode surface. All lipids do not possess each of the regions that are required for linker lipid A and membrane spanning lipids C and D to form a membrane on an electrode surface as set forth on page 2 of the specification. Accordingly, claims 1 and 13 should be limited to only those lipids having the required regions disclosed in page 2 of the specification.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite. The claim is not clear as to the composition of "Linker Lipid A", "membrane spanning lipid C", and "membrane spanning lipid D". Any lipid can be considered one of the linking or membrane spanning lipids. In line 3, the recitation of "or similar molecule" is vague and indefinite as it is not clear as to what molecules can be substituted for disulfides of mercaptoacetic acid. The last part of step (1) is also confusing because it

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characterizes any the materials listed in the first three lines of step (1) as ion channels or ionophores and also suggests that any linker molecules, ion channel, or ionophores can be used to form the solution of step (1).

Claim 13 is vague and indefinite. Step (2) recites absorbing disulfide containing components onto the gold surface of the electrode. However, the only disulfide containing component in the solution formed in step (1) is the mercaptoacetic acid. Only mercaptoacetic acid is absorbed onto the gold surface?

Claim 14 is vague and confusing. Claim 13 does not recite 2-mercaptoethanol but claim 14 recites its presence in the solution formed in step (1) of claim 13. Also, is the 70% referring to membrane spanning lipid C or membrane spanning lipid D?

Claim 18 is vague and indefinite. The recitation of “or similar spacer molecule” is not clear as to what molecules can be substituted for MAAD. The recitation of “such as EDS” is vague and indefinite as it is not clear as to whether the phrase is limiting or merely exemplary. Furthermore, the abbreviation “EDS” must be defined by generic terminology.

Claims 19 and 21 are vague and indefinite. The abbreviations “DPEPC” and “GDPE” must be defined by generic terminology. The recitation of “or similar molecules” is not clear as to what other molecules can be substituted for the listed molecules.

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Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raguse et al.

Raguse et al (U.S. Patent 5,637,201) disclose a method for producing an electrode membrane. The method comprises (1) forming a solution containing reservoir lipids comprising within the same molecule an attachment region, a hydrophilic region, a hydrophobic region, and optionally a head group; and spacer compounds comprising within the same molecule a hydrophilic group and an attachment group; (2) contacting an electrode with the solution from step (1), the composition of the electrode and the attachment regions being selected such that the attachment regions chemisorb to the electrode; (3) rinsing the electrode; (4) contacting the coated electrode from step (3) with a solution of lipid and ionophore in a carrier solvent containing less than 2% of an alkane; and (5) adding an aqueous solution to the electrode from step (4) (col. 7, lines 15-35). The spacer molecule can be the disulfide of mercaptoacetic acid. The hydrophobic region of a proportion of the reservoir lipids have covalently attached thereto an ionophore via a hydrophobic spacer (col. 7, lines 57-64). Gramicidin B can be used as a linking lipid in the

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solution of step (1) (col. 11, lines 36-45). The electrode is formed of a transition metal, such as gold (col. 5, lines 3-11).

The method of Raguse et al differs from the instant invention in contacting the electrode with a separate solution containing the ionophore (Gramicidin B).

However, it would have been obvious to one of ordinary skill in the art to combine the solutions in steps (1) and (4) of the method of Raguse et al because combining the solutions obviates an additional step to shorten the method.

With respect to the specific ratios of lipids and reagents recited in claims 3-6, 8, 9, and 14, the optimum ratios for forming a membrane can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

7. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raguse et al.

Raguse et al (WO 94/07593) disclose a method for producing an electrode membrane. The method comprises (1) forming a solution containing reservoir lipids comprising within the same molecule an attachment region, a hydrophilic region, a hydrophobic region, and optionally a head group; and spacer compounds comprising within the same molecule a hydrophilic group and an attachment group; (2) contacting an electrode with the solution from step (1), the composition of the electrode and the attachment regions being selected such that the attachment regions chemisorb to the electrode; (3) rinsing the electrode; (4) contacting the coated electrode from step (3) with a solution of lipid and ionophore in a carrier solvent containing less than 2% of an alkane;

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and (5) adding an aqueous solution to the electrode from step (4) (page 13). The spacer molecule can be the disulfide of mercaptoacetic acid. The hydrophobic region of a proportion of the reservoir lipids have covalently attached thereto an ionophore via a hydrophobic spacer (page 14). Gramicidin B can be used as a linking lipid in the solution of step (1) (page 20). The electrode is formed of a transition metal, such as gold (page 9).

The method of Raguse et al differs from the instant invention in contacting the electrode with a separate solution containing the ionophore (Gramicidin B).

However, it would have been obvious to one of ordinary skill in the art to combine the solutions in steps (1) and (4) of the method of Raguse et al because combining the solutions obviates an additional step to shorten the method.

With respect to the specific ratios of lipids and reagents recited in claims 3-6, 8, 9, and 14, the optimum ratios for forming a membrane can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patents 4,824,529; 5,328,847; 5,443,955; 5,591,647

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can


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normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027 or at e-mail address james.housel@uspto.gov. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

chin/cc
November 3, 1997


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800